

**REMARKS**

Claims 1, 3-9, 11, 12, 14-22, 24, 25, and 27-51 will be pending upon entry of this Amendment C. Claims 1, 19, 49, and 51 have been amended to require the solidifying agent to be selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof. Support for these amendments can be found in originally filed claims 10 and 23 and, further in the instant Specification at paragraph [0034]. Additionally, Claims 31-48 and 50 have been withdrawn as directed to a non-elected invention. Applicants expressly reserve the right to file divisional applications directed to these non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

**1. Rejection of the Claim 51 under 35 U.S.C. §103(a)**

Reconsideration is requested of the rejection of claim 51 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755).

Claim 51, as amended herein, is directed to a single-use body treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use body treatment product is a film and further comprises a single layer. The solidifying agent is selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Fox discloses a water soluble sheet or film for use in the personal care field. The water soluble sheets include a "base composition" that includes from about 0.75% to about 5% by weight of a water soluble film forming polymer; from about 6.5%

to about 23% by weight of polyvinyl alcohol; and from about 0.75% to about 12% by weight of a humectant such as propylene glycol.<sup>1</sup> Suitable materials for use as the water soluble film forming polymer include polyvinylpyrrolidone (PVP), polyquaternium 10, magnesium aluminum silicate, VP/VA copolymer, ethyl ester of PVM/MA copolymer, and sodium magnesium silicate.<sup>2</sup> Furthermore, the base composition can be used with a variety of surfactants, which when exposed to water, will dissolve and provide personal cleansing such as can be obtained from a soap bar or a liquid body wash.<sup>3</sup> Significantly, Fox fails to disclose a product comprising **from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material and a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.** These are significant aspects of Applicants' invention.

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<sup>1</sup> U.S. 2004/0071755 at paragraph 9.

<sup>2</sup> *Id.* at paragraph 10.

<sup>3</sup> *Id.* at paragraph 6.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."<sup>4</sup> The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at each and every limitation of the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of

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<sup>4</sup> In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited reference fails to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify the reference to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as recognized by the Office, Fox fails to teach or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. As stated by the Office, however, while the Fox reference fails to specifically teach or suggest a composition having the recited components in the specific weight percentages as claimed in Applicants' claim 51, Fox discloses a composition having components that meet and/or overlap with the ranges as claimed and, as such, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition to arrive at Applicants' claim 51.

Applicants respectfully disagree as Applicants maintain that there is simply nothing in Fox stating that its compositions as disclosed should comprise from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Nor is there any reason for one skilled in

the art, reading Fox to modify the compositions described therein to arrive at a composition that comprises from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material.

The present invention includes water soluble and/or water-dispersible film forming polymeric material in an amount from about 40% to about 70% in order to provide structural integrity to the product such that the product will remain on the lips to provide treatment to the user. Fox, however, is directed to a body wash, which is intended to be rinsed from the skin after application. As such, the high amounts of the water soluble and/or water-dispersible film forming polymeric material would be unnecessary in the composition of Fox, and could actually be considered undesirable as it would hinder the ability of the body wash to be washed from the skin. Accordingly, one skilled in the art would not, and could not, be motivated to modify Fox to include from about 40% to about 70% of a water-soluble and/or water-dispersible polymeric film forming agent.

Moreover, as noted above, the compositions of Fox comprise from about 0.75% to about 5% by weight of a water soluble film forming polymer (e.g., polyvinylpyrrolidone) and from about 6.5% to about 23% by weight of polyvinyl alcohol, which are listed as examples of water-soluble film forming polymeric materials in Applicants' claimed invention. As such, the maximum amount of water-soluble film forming polymeric material for use in the composition as taught in the Fox reference is 28% by weight. Furthermore, as shown in all of the working Examples in the Fox reference, the water soluble film forming polymer is present in the base composition in an amount of about 15.66% by weight

(i.e., 1.75% PVP K-30 + 13.91% AirVol 523S (polyvinyl alcohol)). More specifically, the final products produced in the working Examples of the Fox reference teach even lower amounts of water soluble film forming polymers. Specifically, the working Examples show that the base composition is present in the final composition in amounts of from about 19.5-21% by weight. Thus, the compositions set forth in Fox have significantly lower percentages of water-soluble film forming polymeric materials than the products set forth in Applicants' claim 51. Based on this disclosure, there is no apparent reason for one skilled in the art to avoid preparing the compositions of Fox having less than 40% by weight of water-soluble film forming polymeric material, in direct opposition to the products set forth in Applicants' claim 51.

Furthermore, while the Applicants recognize that the base composition is dried onto the final product, no where in the cited reference is it taught or suggested to what extent the base composition is dried. Specifically, no where in Fox is the final water content of the product disclosed. As such, there is no teaching or suggestion that enough water is removed during the drying process to result in the final product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material as required in claim 51.

Furthermore, as noted above, Fox fails to teach or suggest a solidifying agent as required in Applicants' amended claim 51. More specifically, the single-use lip or body treatment products of the present invention include a solidifying agent in an amount suitable to help solidify the product at or near room temperature. At best, Fox discloses that soap and synthetic

surfactant may be added to the base composition until the point at which film formulation, and consequently, the formation of the soluble sheet product, is adversely effected. Fox continues to explain that soap can be the sole surfactant added to the base composition, or, alternatively, it may be combined with another surfactant for addition to the base composition. Compatible soaps include sodium octonate and potassium soaps. In contrast to the present invention, the purpose of adding the surfactant to the composition of Fox is to aid the disclosed body wash in producing a lather for cleansing. As such, why would one skilled in the art be motivated to modify Fox to include a solidifier from the group as recited in Applicants' amended claim 51, which are included to solidify the presently claimed composition at room temperature? One simply would not, and could not, be so motivated.

As Fox fails to disclose compositions comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material or a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or



polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof, and further, there is no apparent reason for one skilled in the art to modify the compositions of Fox to arrive at the compositions of claim 51, claim 51 is patentable over the Fox reference.

**2. Rejection of the Claims 1, 3-12, 14-18, and 49 under 35 U.S.C. §103(a)**

Reconsideration is requested of the rejection of claims 1, 3-12, 14-18, and 49 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755) in view of Akihiro, et al. (JP 11-209222), and further in view of Kyoko (JP 61-176512).

Claim 1, as amended herein, is directed to a single-use lip treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use lip treatment product is a film and comprises a single layer. The product is capable of being substantially dissolvable on lips in no more than about 50 seconds. The single-use lip treatment product is sized and configured for application to the lips, and the solidifying agent is selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax, C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan

acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Fox is discussed above. Significantly, Fox fails to disclose a composition having the recited components in the specific weight percentages as required in claim 1. Specifically, Fox fails to teach or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material and a solidifying agent as required in Applicants' claim 1. Furthermore, Fox fails to disclose that its final product is sized and configured for application to the lips and is capable of substantially dissolving on lips in no more than about 50 seconds as required in amended claim 1. Recognizing that Fox fails to teach or suggest each and every limitation of Applicants' claim 1, the Office attempts to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness by citing the Akihiro, et al. and Kyoko references for combination with Fox.

Specifically, Akihiro, et al. disclose a humectant pack material for lip treatment. The pack material includes a polymer gel containing from 0.01 to 80 wt.% humectant and from

10 to 95 wt.% water in a polyacrylamide-based polymer.<sup>5</sup> The polymer gel is obtained by carrying out a water-soluble polymerization of an acrylamide-based monomer with an acrylic-acid (meta) amide. Specifically, a cross-linking acrylamide monomer such as N and N'-methylenebis acrylamide, methylenebis methacrylamide, and N'N, N'-ethylene screw acrylamide, [N, and] N and N'-ethylene screw methacrylamide, 1, and 2-JIAKURIRU amide ethylene glycol, is polymerized using an epoxy cross linking agent, such as ethylene glycol diglycidyl ether, polyethylene glycol, diglycidyl ether, triglycidyl 2 hydroxyethyl isocyanurate, trimethylolpropane polyglycidyl ether, glycerol poly glycidyl ether, and sorbitol polyglycidyl ether.<sup>6</sup>

The resulting polymer gel includes less than 0.3% by weight cross linking monomer and less than 3.0% by weight cross linking agent. The pack material including the polymer gel can be fabricated to be in the shape of a lip.<sup>7</sup> Furthermore, the pack material is designed such that the material is adhered onto the surface of the lip and then removed from the lip after a time period of from 0.1 to 10 minutes to provide moisturization.<sup>8</sup>

Significantly, no wherein in the Akihiro, et al. reference, is it taught or suggested for the pack material to be a water-soluble material (such as the material in the Fox reference, and further, in Applicants' claimed invention), capable of solubilizing on the skin for a suitable treatment thereof and,

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<sup>5</sup> JP 11-209222 at abstract.

<sup>6</sup> See translation of *id.* at paragraph 10.

<sup>7</sup> See translation of *id.* at paragraphs 4 and 20. Specifically, as disclosed in paragraph 20, the configuration of the pack material can be an ellipse form, circular, a lip form, a heart form, a hemicycle, a half-ellipse form, a rectangle, etc.

more specifically, no where is it disclosed that the pack material is substantially dissolvable on lips in no more than about 50 seconds. While, as noted above, the polymer gel is obtained by carrying out a water-soluble polymerization; there is nothing to suggest that the resulting gel, and resulting pack material, is water-soluble. Moreover, as noted above, the gel must be **removed** from the surface of the skin after a short period of time has lapsed; that is, the gel will not substantially dissolve upon contact with moisture on the lips. As such, the pack material of Akihiro, et al. is not, and cannot, dissolve on lips in no more than about 50 seconds.

Further, as taught in paragraph 22 of the translated reference, the pack material suitably is configured to have a multi-layer structure. This is in direct opposition to the single layer required in claim 1 (and further, as desired for the composition of Fox, as indicated by the Office in the present Office action).

Moreover, no wherein in the Akihiro, et al. reference, is it taught or suggested for the pack material to contain a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax,

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<sup>8</sup> See translation of *id.* at paragraph 23.

spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Kyoko discloses a film-forming agent comprising a polymeric compound; a humectant; and an oleaginous wax for providing moisture to lips, and to further prevent abnormal drying and chapping of lips.<sup>9</sup> Examples of polymeric compounds that can be used to form the film-forming agent can include PVA, polyvinyl pyrrolidone, and CMC. Furthermore, the humectant has excellent moisture-retainability and is effective to give moistness to the dried skin and can be, for example, glycerol, propylene glycol, polyethylene glycol, and sorbitol. The oleaginous wax is effective in supplying the skin with a moderate amount of oil to prevent chapping of the skin. Suitable waxes include olive oil, jojoba oil, lanoline, and squalane. The skin film is applied to the lip mucous membrane surface and then the skin film is peeled off of the surface of the lip, either prior to or after the film has dried, to treat the lips.<sup>10</sup>

Significantly, as with the Fox and Akihiro, et al. references, Kyoko fails to teach or suggest a composition having from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. At best, Kyoko discloses using 15% or less by weight of a polymer such as poly

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<sup>9</sup> JP 61-176512 at abstract.

<sup>10</sup> See *Id.* (translation) at page 5, lines 9-16.

(vinyl alcohol), polyvinylpyrrolidone, or cellulose.<sup>11</sup> Further, Kyoko fails to teach or suggest a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Additionally, no wherein in the Kyoko is it taught or suggested that its skin film is capable of substantially dissolving on lips in no more than about 50 seconds. Similar to the Akihiro, et al. reference discussed above, the film must be **peeled from** the surface of the lip after a short period of time has lapsed, either prior to or after the film has dried to the surface of the lip; that is, the film will not substantially dissolve upon contact with moisture on the lips.

As noted above, in order for the Office to show a *prima facie* case of obviousness, the Office must show: (1) a finding

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<sup>11</sup> See, e.g., Id. at Examples 1-5. Specifically, water-soluble film forming polymers are present in the compositions in the concentrations as follows: Example 1: 15% by weight; Example 2: 15% by weight; Example 3: 13% by weight; Example 4: 15% by weight; and Example 5: 15% by weight.

that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. As further noted above, this is not a rigid formula as the common sense of those skilled in the art can demonstrate why some combination would have been obvious where others would not. The Office has clearly failed to meet its burden under number (1), as the references, alone or in combination, fail to teach or suggest each and every element of claim 1, and further, there is no apparent reason for one skilled in the art to combine and/or modify the cited references to arrive at Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, none of the cited references, alone or in combination, teach or suggest a film product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Additionally, none of the cited references teach or suggest a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated

microcrystalline wax, hydrogenated rice bran wax, japan wax, lanolin wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof. Furthermore, none of the cited references teach or suggest a film product that is capable of substantially dissolving on the lips in no more than about 50 seconds. Specifically, while both the Fox and Kyoko references disclose water-soluble film forming polymers, the cited references teach using amounts significantly lower than required in Applicants' claim 1.

Furthermore, while the film of the Fox reference can dissolve when exposed to water, the film dissolves to provide for a personal cleansing product such as in the form of a hand soap or body wash, which is then **rinsed** from the skin.<sup>12</sup> No where is it suggested that the film can treat and/or moisturize the skin by substantially dissolving on the skin's surface in no more than about 50 seconds. There is simply no suggestion in the Fox reference that the film can substantially dissolve in no more than about 50 seconds for treatment.

The Akihiro, et al. and Kyoko references fail to overcome the above shortcomings. Specifically, as noted above, no where in the Akihiro, et al. or Kyoko references is it taught or

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<sup>12</sup> See U.S. 2004/0071755 at paragraph 5.



suggested that their products are capable of substantially dissolving on lips in no more than about 50 seconds. More particularly, in direct opposition to claim 1's requirement of the film being capable of substantially dissolving on the lips, the cited references both require that their products be physically peeled or otherwise removed from the surface of the lips to provide treatment. As such, none of the cited references teach or suggest a film product being capable of substantially dissolving on lips in no more than about 50 seconds. Furthermore, as noted above, nowhere in the Akihiro, et al. or Kyoko references is it taught or suggested to include a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax, C<sub>30</sub> alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, lanolin wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Furthermore, Applicants assert that there is no reason or motivation present in either the cited references or in the general knowledge of one ordinarily skilled in the art to

combine and/or modify the cited references to arrive at each and every limitation of claim 1. Specifically, a close reading of the references actually teaches away from the combination as the compositions and products produced in the cited references are designed to solve substantially different problems using different mechanisms. For example, as noted above, to treat the lip/skin using the polymer gel of the pack material of Akihiro, et al. and/or the skin film of Kyoko, Akihiro, et al. and Kyoko teach applying their products to the lip surface, and further peeling the material from the surface after a short period of time.<sup>13</sup> As such, one skilled in the art, reading the Akihiro, et al. and Kyoko references, would not, and could not, reasonably use the polymer gel of Akihiro, et al. nor the film of Kyoko in the compositions of the Fox reference, which are designed to dissolve and lather in water to produce a body cleansing product for cleaning the surface of the skin.

Furthermore, as noted above, the pack material of Akihiro, et al. suitably is configured to have a multi-layer structure. This is in direct opposition to the single layer as desired for the composition of Fox.

In the Office action mailed on January 14, 2008, the Office states that Applicants' arguments that Akihiro et al. fails to teach a water-soluble material in the moisturization pack for dissolving on the lips of a user in no more than about 50 seconds and fails to teach that the pack is configured to a single layered structure are not persuasive as the Akihiro et al. reference was not used to address those particular

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<sup>13</sup> See JP 11-209222 at column 2, lines 32-42, and JP 61-176512 at page 5,

limitations. With all due respect, Applicants disagree as Applicants point to the fact that the Akihiro et al. reference does not teach a water-soluble material in the moisturization pack for dissolving on the lips of a user in no more than 50 seconds, not for showing that Akihiro, et al. fail to teach or suggest each and every limitation, but to show that there would be no reason to combine the Akihiro, et al. reference with the Fox reference. Specifically, as Fox is directed to using a base composition that dissolves when contacted with water, one skilled in the art would not reasonably think to add the components of the composition in Akihiro et al., directed to a composition that is **not** intended to dissolve in water. Similarly, the fact that Akihiro et al. fail to teach a single layered structure also shows that one skilled in the art would have no reason to combine the references as Fox is directed to a single layer product; that is, one skilled in the art, reading Fox, would not reasonably look to a product having a multi-layered structure, such as the product in Akihiro, et al..

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 1 and, further, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

Claims 3-9, 11, 12 and 14-18 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Claim 49 is similar to claim 1 and further requires a water-dispersible film forming polymeric material in combination with the water-soluble film forming polymeric material. As such, claim 49 is patentable for the same reasons as set forth above for claim 1 as well as for the additional elements it requires.

**3. Rejection of the Claims 19-25 and 27-30 under 35 U.S.C. §103(a)**

Reconsideration is requested of the rejection of claims 19-25 and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755) in view of Akihiro, et al. (JP 11-209222) and Kyoko (JP 61-176512), and further in view of Yang et al. (WO 03/030881).

Claim 19 is similar to claim 1, as discussed above, and further requires the water-soluble film forming polymeric material to be pullulan and the moisturizing agent to be glycerin.

The Fox, Akihiro, et al., and Kyoko references are discussed above. Significantly, as discussed above, the Fox, Akihiro, et al., and Kyoko references fail to teach or suggest a product that is capable of substantially dissolving on lips in no more than about 50 seconds. Further, the Fox, Akihiro, et al., and Kyoko references fail to teach or suggest a solidifying agent as required in Applicants' claim 19.

In addition, as noted by the Office, the Fox, Akihiro, et al., and Kyoko references fail to teach or suggest the specific water-soluble film forming polymeric material being pullulan as required in claim 19. Furthermore, the above cited references

fail to provide a reasoning for combining the references to arrive at each and every limitation of Applicants' claimed combination. Yang et al. fail to overcome the above shortcomings.

Specifically, Yang, et al. fail to teach or suggest a film product that is capable of substantially dissolving on lips in no more than about 50 seconds or a solidifying agent as claimed by Applicants' claim 19. Further, Yang, et al. fail to provide motivation or reasoning for combining the cited references to arrive at Applicants' claimed invention.

Yang, et al. disclose an edible, ingestible water-soluble delivery system in the form of a film composition. The film composition comprises a glucan, such as pullulan, and a water-soluble polymer. Furthermore, the film composition can contain a polar solvent and a pharmaceutical active such as for administration to a body surface including a mucous membrane, such as oral, anal, vaginal, ophthalmological, surface of a wound, such as during surgery, and similar surfaces.<sup>14</sup>

Significantly, Yang, et al. fail to teach or suggest a solidifying agent selected from the group set forth in amended claim 19, and further, Yang, et al. fail to teach or suggest a film product that is capable of substantially dissolving on lips in no more than about 50 seconds. Even more specifically, nowhere in Yang, et al. is it taught or suggested that their delivery system can even treat and moisturize lips, which is the specific problem to be solved in the 2 of the 3 previously discussed cited references (as well, as in Applicants' claimed invention). Specifically, as noted above, Yang, et al. is

directed to edible, ingestible systems for delivering an active ingredient. As such, there is nothing in the Yang, et al. reference or in the general knowledge of one ordinarily skilled in the art, that provides for an apparent reason to use the **edible** delivery system of Yang, et al. with the **lip moisturizing** compositions and products of the Akihiro, et al. or Kyoko references, nor with the body wash of the Fox reference.

Furthermore, as with the Akihiro, et al. reference discussed above, the delivery system of Yang, et al. is suitably a multi-layered film. This is in direct contrast to the composition of Fox. As such, one skilled in the art would actually be taught away from combining the Yang, et al. reference and the Fox reference.

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 19, and further, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 19, claim 19 is patentable over the cited references.

Claims 20-22, 24, 25 and 27-30 depend directly from claim 19 and are thus patentable for the same reasons as set forth above for claim 19 as well as for the additional elements they require.

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<sup>14</sup> WO 03/030881 at pages 6-7, lines 32-2.

**CONCLUSION**

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-9, 11, 12, 14-22, 24, 25, 27-30, 49, and 51 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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